

REMARKS

A. Status of the Claims

Claims 1-8, 11-13 and 17-28 were examined and rejected; claims 9, 10, 14-16 and 29-63 were withdrawn from consideration by the Office. Claim 1 has been amended for the reasons set forth below. New claims 64-69 have been added.

B. The Rejected Claims Are Patentable over Barbut

The Office rejects claims 1, 4-7, 11-13, 24 and 27 as being anticipated by U.S. Patent No. 6,379,331 to Barbut *et al.* (Barbut). Applicants have amended claim 1 for the sole purpose of distinguishing Barbut. Claim 1 now recites:

percutaneously introducing a guidewire into the spinal subarachnoid space at an entry location;

percutaneously introducing a device over the guidewire and into the spinal subarachnoid space, the device having a first passageway sized to slidably receive, and work with, at least the guidewire, and the guidewire being positioned in the first passageway; and

advancing the device over the guidewire and within the spinal subarachnoid space at least more than 10 centimeters from the entry location.

Barbut fails to disclose or suggest percutaneously introducing a guidewire into the spinal subarachnoid space, or percutaneously introducing a device over the guidewire and advancing the device over the guidewire and within the spinal subarachnoid space. Barbut discloses only introducing catheter ends over needles. For this reason, claim 1 and its rejected dependent claims are patentable over Barbut.

C. Claim 2 Is Patentable

The Office rejects claim 2 as being obvious over Barbut in view of U.S. Patent No. 6,328,694 to Michaeli. Michaeli does not cure Barbut's failure to disclose or suggest the use of a guidewire. Furthermore, there is no motivation to combine Michaeli's background teaching

about brain tissue removal with the teachings of Barbut, which pertain only to methods and devices that can be used to cool and re-circulate CSF, to arrive at a modified Barbut technique for which no need exists. *See In re Nomiya*, 184 USPQ 607, 612-613 (CCPA 1975) (holding that it is improper to conclude that an invention is obvious absent evidence that one of ordinary skill would have recognized that an underlying problem existed).

D. Claim 3 Is Patentable

The Office rejects claim 3 as being obvious over Barbut in view of U.S. Patent No. 4,904,237 to Janese. Janese does not cure Barbut's failure to disclose or suggest the use of a guidewire.

E. Claims 8, 19 and 20 Are Patentable

The Office rejects claims 8, 19 and 20 as being obvious over Barbut in view of U.S. Patent No. 6,004,262 to Putz *et al.* (Putz). Putz does not cure Barbut's failure to disclose or suggest the use of a guidewire.

Furthermore, one could not introduce an endoscope or detector through either of the catheter ends in Barbut without changing the principle of operation of Barbut. Barbut is designed to create a CSF cooling and re-circulation loop for a patient. Nothing in Barbut even remotely suggests that the introduction of other instruments or structures through his catheters can or should interrupt that process, or that his system should be modified to accept their introduction. The Office is improperly picking and choosing from disparate disclosures to arrive at the claimed subject matter, and its bare assertion for a motivation is not supported by substantial evidence. *See In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001) ("With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment what would be

basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.”); MPEP § 2144.03 at 2100-138 (“It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence on which the rejection was based.”) (citing *In re Zurko*, 258 F.3d at 1386).

F. Claims 17 and 22 Are Patentable

The Office rejects claims 17 and 22 as being obvious over Barbut in view of U.S. Patent No. 5,423,760 to Yoon. Yoon does not cure Barbut’s failure to disclose or suggest the use of a guidewire.

Furthermore, with respect to claim 17, one could not introduce an apparatus through either of the catheter ends in Barbut and apply electric current, heat or cryothermal stimulation to a tissue with the apparatus without changing the principle of operation of Barbut. Barbut is designed to create a CSF cooling and re-circulation loop for a patient. Nothing in Barbut even remotely suggests that the introduction of other structures through his catheters can or should interrupt that process, or that his system should be modified to accept their introduction. The Office is improperly picking and choosing from disparate disclosures to arrive at the claimed subject matter, and its bare assertion for a motivation is not supported by substantial evidence. *See In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001) (“With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.”); MPEP § 2144.03 at 2100-138 (“It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence on which the rejection was based.”) (citing *In re Zurko*, 258 F.3d at 1386).

G. Claim 25 Is Patentable

The Office rejects claim 25 as being obvious over Barbut in view of U.S. Patent No. 6,233,488 to Hess. Hess does not cure Barbut's failure to disclose or suggest the use of a guidewire.

Furthermore, one could not introduce an electrode through either of the catheter ends in Barbut and place the electrode within a living being without changing the principle of operation of Barbut. Barbut is designed to create a CSF cooling and re-circulation loop for a patient. Nothing in Barbut even remotely suggests that the introduction of electrodes through his catheters can or should interrupt that process, or that his system should be modified to accept electrodes for placement. The Office is improperly picking and choosing from disparate disclosures to arrive at the claimed subject matter, and its bare assertion for a motivation is not supported by substantial evidence. *See In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001) ("With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."); MPEP § 2144.03 at 2100-138 ("It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence on which the rejection was based.") (citing *In re Zurko*, 258 F.3d at 1386).

H. Claim 28 Is Patentable

The Office rejects claim 28 as being obvious over Barbut in view of U.S. Patent No. 5,731,284 to Williams. Williams does not cure Barbut's failure to disclose or suggest the use of a guidewire.

Furthermore, one could not introduce genetic material into a patient through either of the catheter ends in Barbut and place the genetic material within the living being to assist in treating a neurologic condition without changing the principle of operation of Barbut. Barbut is designed to create a CSF cooling and re-circulation loop for a patient. Nothing in Barbut even remotely suggests that genetic material introduction through his catheters can or should interrupt that process, or that his system should be modified to allow for the introduction of such material. The Office is improperly picking and choosing from disparate disclosures to arrive at the claimed subject matter, and its bare assertion for a motivation is not supported by substantial evidence. *See In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001) (“With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.”); MPEP § 2144.03 at 2100-138 (“It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence on which the rejection was based.”) (citing *In re Zurko*, 258 F.3d at 1386).

I. New Claims 64-67 Are Patentable

New claims 64-67 correspond to allowable claims 18, 21, 23 and 26 re-written in independent form.

J. New Claims 68-69 Are Patentable

New claim 68 corresponds to original claim 5 re-written in independent form, and new claim 69 corresponds to original claim 6. Original claim 5 was patentable as written. It recited—and claim 68 now recites—accessing at least one ventricle located within the head with a second device introduced **through the passageway of the device**. The only ventricle access

discussed in Barbut appears at col. 4, lines 24-25, col. 9, lines 16-18 and col. 9, line 35. All of these discussions concerning placing the second catheter of Barbut's dual-catheter system into the lateral ventricle through a skull burr hole. The second catheter is not introduced through a passageway in the first catheter in any of these examples. Furthermore, the access to the lateral ventricle disclosed in Barbut is **not** percutaneous access, contrary to the access that would occur in following claim 68. For these reasons, new claims 68 and 69 are patentable over Barbut.

K. Conclusion

Claims 1-8, 11-13, 17-28, and 64-69 are in condition for allowance. Examiner Han is invited to contact the undersigned attorney at (512) 536-3031 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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